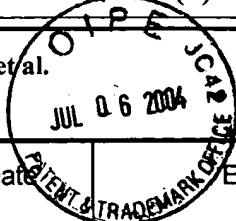


TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT (Under 37 CFR 1.97(b) or 1.97(c))				Docket No. Army172	
In Re Application Of: Ulrich et al.					
Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/002,784	11/26/01	Nita Minnifield	000041022	1645	6261
Title: Bacterial Superantigen Vaccines					
Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450					
37 CFR 1.97(b)					
1. <input checked="" type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.					
37 CFR 1.97(c)					
2. <input type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:					
<div style="margin-left: 40px;"> <input type="checkbox"/> the statement specified in 37 CFR 1.97(e); </div>					
OR					
<div style="margin-left: 40px;"> <input type="checkbox"/> the fee set forth in 37 CFR 1.17(p). </div>					

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.
Army172

In Re Application: Ulrich et al.



Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/002,784	11/26/01	Nita Minnifield	000041022	1645	6261

Bacterial Superantigen Vaccines

Payment of Fee

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of _____ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **21-0380** as described below.
- ☐ Charge the amount of _____
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Certificate of Transmission by Facsimile*

I certify that this document and authorization to charge deposit account is being facsimile transmitted to the United States Patent and Trademark Office (Fax. No. _____)

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***This certificate may only be used if paying by deposit account.**

Signature

Dated: July 6, 2004

Marlana Titus, Reg. No. 35,843
for Elizabeth Arwine, Reg. No. 45,867
Attorney for applicant
U.S. Army Medical Research and Materiel Command
504 Scott Street
Fort Detrick, MD 21702-5012
(301) 977-7227

CC:



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of Ulrich et al.

Appln. No.: 10/002,784

Group Art Unit: 1645

Filed: November 26, 2001

Examiner: N. Minnifield

Title: Bacterial Superantigen Vaccines

* * * * *

July 6, 2004

LETTER ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of Patents
and Trademarks
Alexandria, VA 22313-1450

Sir:

Supplemental to the Information Disclosure Statement and PTO-1449 Form submitted July 6, 2004, along with the Request for Continued Examination, we submit the following comments regarding the references cited on the PTO-1449 Forms and submitted.

Among the references cited in the PTO-1449 form, the following are considered to likely be found the most relevant to allowed claims 32 and 43:

Kappler et al., "VB-Specific Stimulation of Human T Cells by Staphylococcal Toxins", 1989, Science, vol 244, pages 811-813.

Karlsson, et al., "Kinetic analysis of monoclonal antibody-antigen interactions with a new biosensor based analytical system", J. Immunological Methods, 145 (1991), pages 229-240.

Jonsson et al., "Real-Time Biospecific Interaction Analysis Using Surface Plasmon Resonance and a Sensor Chip Technology", Biotechniques, Vol. 11, No. 5, 1991, pages 620-627.

Prasad et al., "Structure of Toxic Shock Syndrome Toxin 1", Biochemistry, Accelerated Publications, Vol. 32, No. 50, 1993, pages 13761-13766.

Acharya, et al., "Structural basis of superantigen action inferred from crystal structure of toxic-shock syndrome toxin-1", Nature, Vol. 367, Jan. 6, 1994, pages 94-97.

Swaminathan et al., "Crystal structure of staphylococcal enterotoxin B, a superantigen", *Nature*, Vol. 359, October 29, 1992, pages 801-806.

Ulrich et al., "Staphylococcal enterotoxins A and B share a common structural motif for binding class II major histocompatibility complex molecules", *Nature Structural Biology*, Vol. 2, No. 6, June 1995, pages 554-560.

Kuo et al., "Role of Streptococcal Pyrogenic Exotoxin B in the Mouse Model of Group A Streptococcal Infection", *Infection and Immunity*, Aug. 1998, Vol. 66, No. 8, pages 3931-3935.

Kapur et al., "A conserved Streptococcus pyogenes extracellular cysteine protease cleaves human fibronectin and degrades vitronectin", *Microbial Pathogenesis*, 1993, Vol. 15, pages 327-346.

Kapur et al., "Cleavage of interleukin 1B (IL-1B) precursor to produce active IL-1B by a conserved extracellular cysteine protease from Streptococcus pyogenes", *Proc. Natl. Acad. Sci. USA*, Vol. 90, August 1993, pages 7676-7680.

Kagawa et al., "Crystal structure of the zymogen form of the group A Streptococcus virulence factor SpeB: And integrin-binding cysteine protease", *PNAS*, Feb. 29, 2000, Vol. 97, No. 5, pages 2235-2240.

Gubba et al., "Replacement of Histidine 340 with Alanine Inactivates the Group A Streptococcus Extracellular Cysteine Protease Virulence Factor", *Infection and Immunity*, June 2000, Vol. 68, No. 6, pages 3716-3719.

Stiles et al., "Toxicity of Staphylococcal Enterotoxins Potentiated by Lipopolysaccharide: Major Histocompatibility Complex Class II Molecule Dependency and Cytokine Release", *Infection and Immunity*, Dec. 1993, Vol. 61, No. 12, pages 5333-5338.

Baker et al., "Structural features of a zinc binding site in the superantigen streptococcal pyrogenic exotoxin A (SpeA1): Implications for MHC class II recognition", *Protein Science*, 2001, Vol. 10, pages 1268-1273.

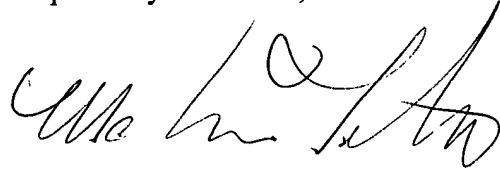
Roggiani, et al., "Analysis of Toxicity of Streptococcal Pyrogenic Exotoxin A Mutants", *Infection and Immunity*, July 1997, Vol. 65, No. 7, pages 2868-2875.

Kline et al., "Analysis of the Superantigenic Activity of Mutant and Allelic Forms of Streptococcal Pyrogenic Exotoxin A", *Infection and Immunity*, Vol. 64, No. 3, March 1996, pages 861-869.

We provide this suggestion that these references are likely more relevant than the others submitted today, only for the purpose of being helpful to the Examiner. We understand that the Examiner, upon review of all of the references, may deem that different or additional references may be more relevant to examination.

If the Examiner has any questions, or would like to discuss any of the references, she is invited to contact the applicant's representative Marlana K. Titus, at 301-977-7227. **(Please note that this is a new telephone number.)**

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Marlana Titus', with a stylized flourish at the end.

Marlana Titus, Reg. No. 35,843
For Elizabeth Arwine, Reg. No. 45,867
Attorney for Applicant
U.S. Army Medical Research and Materiel
Command, Attn: MCMR-JA
Fort Detrick, Maryland 21702-5012

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Nash & Titus, LLC
(301) 977-7227

INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>				Docket Number (Optional) Army172		Application Number 10/002,784		
				Applicant(s) Ulrich et al.				
				Filing Date November 26, 2001		Group Art Unit 1645		
U.S. PATENT DOCUMENTS								
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
U.S. PATENT APPLICATION PUBLICATIONS								
*EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
FOREIGN PATENT DOCUMENTS								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation	
							YES	NO
OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>								
	A	Kappler et al., "VB-Specific Stimulation of Human TCells by Staphylococcal Toxins", 1989, Science , vol 244, pages 811-813.						
	B	Karlsson, et al., "Kinetic analysis of monoclonal antibody-antigen interactions with a new biosensor based analytical system", J. Immunological Methods, 145 (1991), pages 229-240.						
EXAMINER				DATE CONSIDERED				
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*EXAMINER INITIAL	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)
C	Johnson et al., "Real-Time Biospecific Interaction Analysis Using Surface Plasmon Resonance nad a Sensor Chip Technology", Biotechniques, Vol. 11, No. 5, 1991, pages 620-627.
D	Prasad et al., "Structure of Toxic Shock Syndrome Toxin 1", Biochemistry, Accelerated Publications, Vol. 32, No. 50, 1993, pages 13761-13766.
E	Acharya, et al., "Structural basis of superantigen action inferred from crystal structure of toxic-shock syndrome toxin-1", Nature, Vol. 367, Jan. 6, 1994, pages 94-97.
F	Swaminathan et al., "Crystal structure of staphylococcal enterotoxin B, a superantigen", Nature, Vol. 359, October 29, 1992, pages 801-806.
G	Ulrich et al., "Staphylococcal enterotoxins A and B share a common structural motif for binding class II major histocompatibility complex molecules", Nature Structural Biology, Vol. 2, No. 6, June 1995, pages 554-560.
H	Kuo et al., "Role of Streptococcal Pyrogenic Exotoxin B in the Mouse Model of Group A Streptococcal Infection", Infection and Immunity, Aug. 1998, Vol. 66, No. 8, pages 3931-3935.
I	Kapur et al., "A conserved Streptococcus pyogenes extracellular cysteine protease cleaves human fibronectin and degrades vitronectin", Microbial Pathogenesis, 1993, Vol. 15, pages 327-346.
J	Kapur et al., "Cleavage of interleukin 1B (IL-1B) precursor to produce active IL-1B by a conserved extracellular cysteine protease from Streptococcus pyogenes", Proc. Natl. Acad. Sci, USA, Vol 90, August 1993, pages 7676-7680.
K	Kagawa et al., "Crystal structure of the zymogen form of the group A Streptococcus virulence factor SpeB: And integrin-binding cysteine protease", PNAS, Feb. 29, 2000, Vol. 97, No. 5, pages 2235-2240.
L	Gubba et al., "Replacement of Histidine 340 with Alanine Inactivates the Group A Streptococcus Extracellular Cysteine Protease Virulence Factor", Infection and Immunity, June 2000, Vol. 68, No. 6, pages 3716-3719.
M	Stiles et al., "Toxicity of Staphylococcal Enterotoxins Potentiated by Lipopolysaccharide: Major Histocompatibility Complex Class II Moelcule Dependency and Cytokine Release", Infection and Immunity, Dec. 1993, Vol. 61, No. 12, pages 5333-5338.
N	Baker et al., "Structural features of a zinc binding site in the superantigen streptococcal pyrogenic exotoxin A (SpeA1): Implications for MHC class II recognition," Protein Science, 2001, Vol. 10, pages 1268-1273.

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*EXAMINER INITIAL	OTHER DOCUMENTS	(Including Author, Title, Date, Pertinent Pages, Etc.)
O		Rosigiani, et al., "Analysis of Toxicity of Streptococcal Pyrogenic Exotoxin A Mutants", Infection and Immunity, July 1997, Vol. 65, No. 7, pages 2868-2875.
P		Kline et al., "Analysis of the Superantigenic Activity of Mutant and Allelic Forms of Streptococcal Pyrogenic Exotoxin A", Infection and Immunity, Vol. 64, No. 3, March 1996, pages 861-869.
Q		Schlievert, "Role of Superantigens in Human Disease", J. of Infectious Diseases, 1993, Vol. 163, pages 997-1002.
R		Schlievert et al., "Identification and Characterization of an Exotoxin from Staphylococcus aureus associated with Toxic-Shock Syndrome", J. Infectious Diseases, Vol 143, No. 4, April 1981.
S		Schwab et al., "Superantigen Can Reactivate Bacterial Cell Wall-Induced Arthritis", J. Immunology, Vol. 150, No. 9, May 1, 1993, pages 4151-4159.
T		Karlsson et al., "Kinetic analysis of monoclonal antibody-antigen interactions with a new biosensor based analytical system", J. Immunological Methods, Vol. 145 (1991), pages 229-240.
U		Nabozny et al., "HLA-DQ8 Transgenic Mice Are Highly Susceptible To Collagen-induced Arthritis: A Novel Model For Human Polyarthritis", J. Exp. Med, Vol. 183, Jan. 1996, pages 27-37.
V		Hudson et al., "Two Adjacent Residues in Staphylococcal Enterotoxins A and E Determine T Cell Receptor VB Specificity", J. Exp. Med., Vol. 177, Jan. 1993, pages 175-184.
W		Panina-Bordignon et al., "Identification of HLA-DRalpha Chain Residues Critical for Binding of the Toxic Shock Syndrome Toxin Superantigen", J. Exp. Med., Vol. 176, Dec. 1992, pages 1779-1784.
X		Yakei, et al., "Intravenous Immunoglobulin Contains Specific Antibodies Inhibitory to Activation of T Cells by Staphylococcal Toxin Superantigens", J. Clin. Invest., vol. 91, Feb. 1993, pages 602-607.
Y		Sundstrom, et al., "The Co-crystal Structure of Staphylococcal Enterotoxin Type A With Zn ²⁺ at 2.7 A Resolution", J. Biological Chemistry, vol 271, No. 50, Dec. 13, 1996, pages 32212-32216.
Z		Gubba et al., "Replacement of Histidine 340 with Alanine Inactivates the Group A Streptococcus Extracellular Cysteine Protease Virulence Factor", Infection and Immunity, Vol. 68, No. 6, June 2000, pages 3716-3719.

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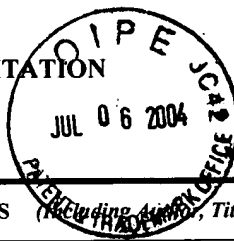
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		Filing Date November 26, 2001	Group Art Unit 1645

*EXAMINER INITIAL	OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
AA	<p>Chang et al., "A Globally Disseminated M1 Subclone of Group A Streptococci Differs from Other Subclones by 70 Kilobases of Prophage DNA and Capacity for High-Frequency Intracellular Invasion," Infection and Immunity, Vol. 66, No. 11, Nov. 1998, pages 5592-5597.</p>	
BB	<p>Kuo et al., "Role of Streptococcal Pyrogenic Exotoxin B in the Mouse of Group A Streptococcal Infection", Infection and Immunity, Vol. 66, No. 8, Aug. 1998, pages 3931-3935.</p>	
CC	<p>Harokopakis et al., "Mucosal Immunogenicity for a Reombinant Salmonella typhimurium-cloned Heterologous Antigen in the Absence of Presence of Coexpressed Cholera Toxin A2 and B Subunits", Infection and Immunity, April 1997, Vol. 65, No. 4, pages 1445-1454.</p>	
DD	<p>Bavari and Ulrich, "Staphylococcal Enterotoxin A and Toxic Shock Syndrome Toxin Compete with CD4 for Human Major Histocompatibility Complex Class II Binding", Infection and Immunity, Feb. 1995, Vol. 63, No. 2, pages 423-429.</p>	
EE	<p>Stiles, et al., "Toxicity of Staphylococcal Enterotoxins Potentiated by Lipopolysaccharide: Major Histocompatibility Complex Class II Molecule Dependency and Cytokine Release", Infection and Immunity, Dec. 1993, Vol. 61, No. 12, pages 5333-5338.</p>	
FF	<p>Taneja and David, "HLS class II transgenic mice as models of human diseases", Immunological Reviews 1999, Vol. 169, pages 67-79.</p>	
GG	<p>Takimoto et al, "Stimulation of all T cells bearing VB1, VB3, VB11 and Vb12 by staphylococcal enterotoxin A", Eur. J. Immunol., 1990, Vol. 20, pages 617-621.</p>	
HH	<p>Sundstrom et al., "The crystal structure of staphylococcal enterotoxin type D reveals Zn2+-mediated homodimerization", The EMBO Journal, Vol. 15, No. 24, pages 6832-6840, 1996.</p>	
II	<p>Bavari et al., "Divergence of Humand and Nonhumand Primate Lymphocyte Responses to Bacterial Superantigens", Clinical Immunology and Immunopathology, Vol. 76, No. 3, Sept. 1995, pages 248-254.</p>	
JJ	<p>Carlsson and Sjogren, "Kinetics of IL-2 and Interferon-γ Production, Expression of IL-2 Receptors, and Cell Prloiferation in Human Mononuclear Cells Exposed to Staphylococcal Enterotoxin A", Cellular Immunology, 96, pages 175-183 (1985).</p>	
KK	<p>White et al., "The VB-Specific Superantigen Staphylococcal Enterotoxin B: Stimulation of Mature T Cells and Clonal Deletion in Neonatal Mice", Cell, Vol. 56, Jan. 13, 1989, pages 27-35.</p>	
LL	<p>Jonsson et al., "Real-Time Biospecific Interaction Analysis Using Surface Plasmon Resonance and a Sensor Chip Technology" BioTechniques, Biofeature, Vol. 11, No. 5, 1991, pages 620-627.</p>	
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MM

Prasad et al., "Structure of Toxic Shock Syndrome Toxin 1", Biochemistry, Accelerated Publications, Vol. 32, No. 50, Dec. 21, 1993, pages 13761-13766.

NN

Herman et al., "Superantigens: Mechanism of T-Cell Stimulation of Role in Immune Responses", Annu. Rev. Immunol., 1991, Vol. 9, pages 745-772.

OO

Kreiswirth et al., "Cloning and expression of streptococcal pyrogenic exotoxin A and staphylococcal toxic shock syndrome toxin-1 in Bacillus subtilis", Mol. Gen. Genit. (1987), Vol. 208, pages 84-87.

PP

Bohach et al., "Staphylococcal and Streptococcal Pyrogenic Toxins Involved in Toxic Shock Syndrome and Related Illnesses", Microbiology, 1990, Vol. 17, Issue 4, pages 251-272.

QQ

Bergdoll, "Enterotoxins", Staphylococci and Staphylococcal Infections, 2, chapter 16, pages 559-598, (1983).

RR

Anderson et al., "Delivery of the Pertactin/P.69 polypeptide of Bordetella pertussis using an attenuated Salmonella typhimurium vaccine strain: expression levels and immune response", Vaccine, 1996, Vol. 14, No. 14, pages 1384-1390.

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TT

Posnett, "Do superantigens play a role in autoimmunity?", seminars in Immunology, Vol. 5, 1993, pages 65-72.

UU

Kim et al., "Toxic Shock Syndrome Toxin-1 Complexed with a Class II Major Histocompatibility molecule HLA-DR1", Science, Nov. 266, Dec. 16, 1994, pages 1870-1874.

VV

Marrack and Kappler, "The Staphylococcal Enterotoxins and Their Relatives", Sciences, Vol. 248, Articles, May 11, 1990, pages 705-711.

WW

Mollick et al., "Class II MHC Molecules Are Specific Receptors for Staphylococcus Enterotoxin A", Science, Vol 244, Reports, May 19, 1989, pages 817-820.

XX

Kappler et al., "VB-Specific Stimulation of Human T Cells by Staphylococcal Toxins", Science, Vol. 244, Reports, May 19, 1989, pages 811-813.

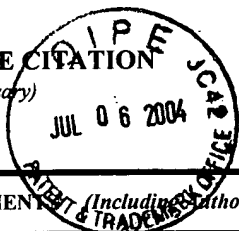
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YY

Kagawa et al., "Crystal structure of the zymogen form of the group A Streptococcus virulence factor SpeB: An integrin-binding cysteine protease", PNAS, Vol. 97, No. 5, Feb. 29, 2000, pages 2235-2240.

ZZ

Medaglini et al., "Mucosal and systemic immune responses to a recombinant protein expressed on the surface of the oral commensal bacterium Streptococcus gordonii after oral colonization", PNAS, USA, Vol. 91, July 1995, pages 6868-6872.

AAA

Kapur, et al., "Cleavage of interleukin 1B (IL-1B) precursor to produce active IL-1B by a conserved extracellular cysteine protease from Streptococcus pyogenes", PNAS, Sci, USA, Vol. 90, Aug. 1993, pages 7676-7680.

BBB

Fraser et al., "Zinc regulates the function of two superantigens", PNAS, Sci, USA, Vol 89, June 1992, pages 5507-5511.

CCC

Choi et al., "Interaction of Staphylococcus aureus toxin 'superantigens' with human T cells", PNAS Sci. USA, Vol. 86, Nov. 1989, pages 8941-8945.

DDD

Goldenberg and Reed, "Bacterial Arthritis", The New England Journal of Medicine, Vol. 312, No. 12, March 21, 1985, pages 764-771.

EEE

Ulrich et al., "Staphylococcal enterotoxins A and B share a common structural motif for binding class II major histocompatibility complex molecules", Nature Structural Biology, Vol. 2. No. 6, June 1995, pages 554-560.

FFF

Jardetzky et al., "Three-dimensional structure of a human class II histocompatibility molecule complexed with superantigen", Nature, Vol. 368, April 21, 1994, pages 711-718.

GGG

Acharya et al., "Structural basis of superantigen action inferred from crystal structure of toxic-shock syndrome toxin-1", Nature, Vol 367, Jan. 6, 1994, pages 94-97.

HHH

Swaminathan et al., "Crystal structure of staphylococcal enterotoxin B, a superantigen", Nature, Vol. 359, Oct. 29, 1992, pages 801-806.

III

Kawabe and Ochi, "Programmed cell death and extrathymic reduction of VB8+ CD4+ T cells in mice tolerant to Staphylococcus aureus enterotoxin B", Nature, Vol. 349, Jan 17, 1991, pages 245-248.

JJJ

Fraser, "High-affinity binding of staphylococcal enterotoxins A and B to HLA-DR", Nature, Vol. 339, May 18, 1989, pages 221-223.

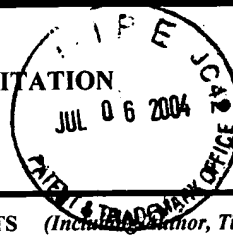
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Kapur et al., "A conserved Streptococcus pyogenes extracellular cysteine protease cleaves human fibronectin and degrades vitronectin", Microbial Pathogenesis, Vol. 15, 1993, pages 327-346.

LLL

Schievert, "Staphylococcal enterotoxin B and toxic-shock syndrome toxin-1 are significantly associated with non-menstrual TSS", The Lancet, May 17, 1986, pages 1149-1150.

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